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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,862	01/30/2002	Michel Gau	HOE-676	6870

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/08/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

<b>Office Action Summary</b>	<b>Application No.</b> 10/060,862	<b>Applicant(s)</b> GAU, MICHEL	
	<b>Examiner</b> Cheryl Miller	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 10-12 and 17-22 is/are rejected.
- 7) ☐ Claim(s) 13-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 11, 12, 17, 18, 19, 20, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "its plane" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the narrow side" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "several identical balls" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether the balls are referring to the spherical body, or if the balls are different.

Claim 18 recites the limitation "the sets of balls" and "the arrangement" in lines 12 and 13 respectively. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the balls" in lines 3 and 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 recites the limitation "the movable body" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the movable body" to recite --the movable spherical body--.

Claim 21 recites the limitation "balls" "the artificial nucleus" and "the cavity" in lines 11, 15, and 16 respectively. There is insufficient antecedent basis for this limitation in the claim. Claim 22 depends upon claim 21 and inherits all problems associated with the parent claim.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 17, 19, 20, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (USPN 5,755,797, cited by applicant in IDS). Referring to claim 10, Baumgartner discloses an intervertebral nucleus prosthesis (col.1, lines 10-13) consisting of at least one spherical body (7) movable in two directions of a plane made of a rigid, non-oxidizing, biocompatible material (col.2, lines 1-4, 13-15, 53-56), with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center (col.2, lines 5-9) in a cage (10, 20, or 22) and protruding at both opposite sides in the form of a spherical cap from the cage (fig.6, 8).

Referring to claim 11, Baumgartner discloses a cage (10, 20, 22) that is curved in a plane and symmetrical to a transverse center plane (fig.6, 8).

Referring to claim 17, Baumgartner discloses a cage (10 or 22) with an isosceles trapezoid shape (col.4, lines 43-46) and holds several balls (7) that touch and are located at both sides of the cage at corners of an isosceles triangle (col.4, lines 5-8).

Referring to claim 19, Baumgartner discloses a cage (10, 20, or 22) consisting of a single component or several components combined with balls (7), having a volume like the volume of the biological nucleus, allowing self-positioning of the prosthesis (fig.1, 2).

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Referring to claim 20, Baumgartner discloses a spherical cap having a height approximately one tenth of a diameter of the spherical body (diameters may vary, col.4, lines 1-8).

Referring to claim 21 and 22, Baumgartner discloses a method for implanting an intervertebral nucleus (col.1, lines 10-15) for insertion of the prosthesis by making an incision endoscopically in the annulus (4) between two vertebral bodies (fig.1, 3), providing an opening (30) large enough to remove and replace the nucleus (col.1, lines 50-54), and closing the opening (col.4, lines 37-39), wherein the opening may be closed with a suture (11, even though Baumgartner does not explicitly disclose a suture used to close the opening, it is so well known in the art and is obvious if not inherent to use a suture to close any tissue openings in the body).

Claims 10, 11, 12, 17, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (USPN 5,320,644). See figures 8, 9, and respective portions of the specification. Referring to claim 10, Baumgartner discloses an intervertebral nucleus prosthesis (1) consisting of at least one spherical body (9, a portion of 1; see figures 8, 9) movable in two directions of a plane made of a rigid, non-oxidizing, biocompatible material (col.2, lines 13-14; col.3, lines 1-2), with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center (col.3, lines 29-32, even though the implant is rotating as one piece, the sphere does rotate about its center) in a cage (volume of 1 outside of volume 9) and protruding at both opposite sides in the form of a spherical cap from the cage (fig.8).

Referring to claim 11, Baumgartner discloses a cage that is curved in a plane and symmetrical to a transverse center plane (fig.8).

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Referring to claim 12, Baumgartner discloses a cage with an isosceles trapezoid shape (fig.9), facilitating displacement in the disc plane and preventing rotation of the prosthesis about its center (col.3, lines 20-32).

Referring to claim 17, Baumgartner discloses a cage with an isosceles trapezoid shape (fig.9) and holds several balls (9; fig.9) that touch and are located at both sides of the cage at corners of an isosceles triangle.

Referring to claim 19, Baumgartner discloses a cage consisting of a single component or several components combined with balls, having a volume like the volume of the biological nucleus, allowing self-positioning of the prosthesis.

Referring to claim 20, Baumgartner discloses a spherical cap having a height approximately one tenth of a diameter of the spherical body (fig.8).

Claims 10, 11, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahrens Uwe (DE 19527975, cited by applicant in IDS). Referring to claim 10, Ahrens Uwe discloses an intervertebral nucleus prosthesis (fig.1, 2, total replacement joints for knee, hip, shoulder, or *other* joints, wherein the vertebral nucleus is a well known joint, abstract, col.1, lines 1-7) consisting of at least one spherical body (1) movable in two directions of a plane made of a rigid, non-oxidizing, biocompatible material, with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center (col.3, lines 1-2) in a cage (2, 3) and protruding at both opposite sides in the form of a spherical cap from the cage (fig.1, 2).

Referring to claim 11, Ahrens Uwe discloses a cage (2, 3) that is curved in a plane and symmetrical to a transverse center plane.

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Referring to claim 20, Ahrens Uwe discloses a spherical cap (top and bottom portions of 1) having a height approximately one tenth of a diameter of the spherical body (fig. 1, 2).

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bristol-Myers Squibb Company (EP 0577179 A1, cited by applicant in IDS). Referring to claim 10, Bristol-Myers Squibb discloses an intervertebral nucleus prosthesis (1) consisting of at least one spherical body (2) movable in two directions of a plane made of a rigid, non-oxidizing, biocompatible material (col. 1, lines 4-6), with a diameter adapted to a biological nucleus, the spherical body being mounted non-displaceably but freely rotatably about its center (fig. 3 has shown an embodiment with flattened portions, which prevent rotation, col. 2, lines 19-27, however since the embodiments in fig. 1 and 2 are spherical, they will inherently rotate) in a cage (6) and protruding at both opposite sides in the form of a spherical cap from the cage (fig. 1).

Referring to claim 11, Bristol Myers Squibb discloses a cage that is curved in a plane and symmetrical to a transverse center plane (fig. 1, 2).

#### ***Allowable Subject Matter***

Claim 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 13-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

August 4, 2003

**BRUCE SNOW  
PRIMARY EXAMINER**